

## **REMARKS**

The amendments are made without prejudice or disclaimer of the canceled subject matter. Applicants reserve the right to file a continuing or divisional application on any subject matter canceled by way of amendment. Applicants respectfully request reconsideration of the present application in light of the foregoing amendments and following remarks.

### **1. Status of the Claims**

The status of the claims following entry of the amendment is as follows:

**Claims canceled:** Claims 1-13 and 16

**Claims pending:** Claims 14-15 and 17

**Claims allowed:** None

**Claims rejected:** Claims 12-15 and 17

**Claims withdrawn:** None

### **2. Support for the Amendments**

The amendments to claim 17 are supported throughout the application. Support for contacting P-LAP positive ovarian carcinoma tissues with an anti-P-LAP antibody is found, for example, at Example 2 of the specification. Support for the recitation "determining that a ten-year disease-free survival rate (DFS) of said patient decreases as the intensity of the specific antigen-antibody binding increases" is found, for example, at page 18, lines 12-15, of the specification. The amendments thus are fully supported in the application as filed and do not introduce impermissible new matter.

### **3. Withdrawal of Finality and Previous Rejections**

The Office withdraws the finality of the Office Action dated December 14, 2007, and the anticipation rejection of claims 11-15 in the prior Office Action.

### **4. Rejection under 35 U.S.C. § 102(a)**

Claims 12-15 and 17 are newly rejected under 35 U.S.C. § 102(a) as allegedly anticipated by Suzuki *et al.*, *Clin. Cancer Res.* 9: 1528-34 (April 2003) ("Suzuki"). The rejection of claims 12 and 13 is mooted by cancellation of the claims without prejudice or disclaimer.

The Office alleges that Suzuki discloses steps (a) and (b) of the claimed method, but the Office acknowledges that Suzuki does not teach step (c). The Office discounts this fact by alleging that step (c) "is a mental step [implied] by Suzuki." Last paragraph on page 3, Office Action. Although the Office fails to explain its rationale, the Office presumably alleges that step (c) does not have patentable weight under 35 U.S.C. § 101 because it is a mental step.

The Office cannot break part claim elements and analyze each element separately for compliance with 35 U.S.C. § 102 and 35 U.S.C. § 101:

[The Supreme] Court has made clear that it is inappropriate to determine the patent-eligibility of a claim as a whole based on whether selected limitations constitute patent-eligible subject matter. *Flook*, 437 U.S. at 594 ("Our approach to respondent's application is, however, not at all inconsistent with the view that a patent claim must be considered as a whole."); *Diehr*, 450 U.S. at 188 ("It is inappropriate to dissect the claims into old and new elements and then to ignore the presence of the old elements in the analysis."). After all, even though a fundamental principle itself is not patent-eligible, processes incorporating a fundamental principle may be patent-eligible. Thus, it is irrelevant that any individual step or limitation of such processes by itself would be unpatentable under § 101. See *In re Alappat*, 33 F.3d 1526, 1543-44 [31 U.S.P.Q.2d 1545] (Fed. Cir. 1994) (en banc) (citing *Diehr*, 450 U.S. at 187). *In re Bilski*, 88 U.S.P.Q.2d 1385, 1394 (Fed. Cir. 2008) (en banc).

Step (c) must be considered in the analysis under 35 U.S.C. § 102. It cannot be discounted on the basis that it is a "mental step." To the extent the Office discounts step (c) under 35 U.S.C. § 101 as a mental step, the rejection is inconsistent with the law and accordingly is improper.

To establish a *prima facie* case of anticipation, a single prior art reference must teach each and every element of the claimed invention, either explicitly or inherently. *Verdegaal Bros. Inc. v. Union Oil Co.*, 814 F.2d 628, 631, 2 U.S.P.Q.2d 1051, 1053 (Fed. Cir. 1987). Inherency may not be established on the basis of possibilities or probabilities. See, e.g., *In re Oelrich*, 666 F.2d 578, 581-82 (C.C.P.A. 1981). In the present case, Suzuki does not teach correlating P-LAP with ten-year disease free survival (DFS), as recited in step (c). The Office nevertheless alleges that the skilled artisan would infer a correlation between increased expression of P-LAP and decreased survival rates. Office Action, p. 3, ¶ 3. To the extent the Office alleges that step (c) is an inherent feature of Suzuki's process, the Office errs. A presumed inference by the skilled artisan of a possible correlation cannot take the place of an

anticipating teaching in Suzuki, because the Office cannot establish inherent anticipation on the basis of such possibilities or probabilities. *See Oelrich*, 666 F.2d at 581-82.

Finally, Suzuki teaches that the expression of P-LAP increases with the grade of endometrial adenocarcinoma. Suzuki, Abstract; Fig. 1. Suzuki teaches contacting anti-human P-LAP antibodies with human tissues from patients with atypical endometrial hyperplasia or endometrial endometrioid adenocarcinoma. Suzuki, p. 1528, 2<sup>nd</sup> col.; p. 1529, 1<sup>st</sup> col. Suzuki does not teach contacting P-LAP-positive *ovarian* carcinoma tissues obtained from a patient with an anti-P-LAP antibody, as recited. Because Suzuki does not teach every element of claim 17, it does not anticipate the claim, and the rejection accordingly should be withdrawn. *See Verdegaal Bros.*, 814 F.2d at 631, 2 U.S.P.Q.2d at 1053.

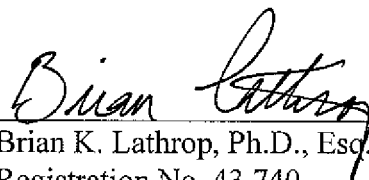
The rejection is improper for all the reasons above. Applicant requests withdrawal of the rejection and allowance of the claims.

### CONCLUSION

The application is believed to be in condition for allowance. If there are any other fees due in connection with the filing of this response, please charge the fees to our Deposit Account No. 50-0573. If a fee is required for an extension of time under 37 C.F.R. § 1.136 not accounted for above, such an extension is respectfully requested and the fee should also be charged to our Deposit Account. If any issues remain outstanding, the Examiner is invited to contact the undersigned attorney, who signs in his authority under 37 C.F.R. § 1.34(b).

Respectfully submitted,

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